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10/618,331	07/11/2003	Laurence Du-Thumm	IR 7050-00	5282

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EXAMINER

KRASS, FREDERICK F

ART UNIT	PAPER NUMBER
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1614

DATE MAILED: 04/07/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/618,331

Applicant(s)

DU-THUMM ET AL.

Examiner

Frederick F. Krass

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 09 January 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 11-46 is/are pending in the application.
- 4a) Of the above claim(s) 12-15 and 19 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 11, 16-18 and 20-46 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date <u>01/25/06</u> . | 6) <input type="checkbox"/> Other: _____ |

Previous Rejections

Unless specifically maintained infra, all previous rejections are withdrawn.

Election by Original Presentation

Newly submitted claims 12-15 and 19 are directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: they recite the use of enzymes other than papain, the species constructively elected by original presentation (as the only specific enzyme originally recited in a dependent claim). The newly added enzymes are patentably distinct from papain insofar as they function by different mechanisms therefrom; a carbohydrase does not reasonably suggest papain (a proteolytic enzyme) on its face, for instance.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 12-15 and 19 are withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

Indefiniteness Rejection (New)

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 27 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 27, the term dipeptide “based” is indefinite insofar as the term “based” is appended to an otherwise definite term, making its modifying function unclear. Since the term “based” is not necessary to an understanding of the claimed subject matter, the examiner recommends deleting it.

Obviousness Rejection (New)

1) Claims 11, 16-18, 20-25, 28-43 and 46 are rejected under 35 U.S.C. 103(a) as being obvious over Hernandez (ES 2 131 006) in view of Gebreselassie et al (USP 6,379,654).¹

The primary reference has been discussed at length in the previous Office action, and discloses chewing gums and tablets comprising 18-21 percent gum base (chicle) and containing 1-5 percent by weight papain, wherein the papain is

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incorporated at relatively low temperature (40 to 60 degrees Celsius) in order to prevent thermal destabilization.² Glycerin may be used as a humectant in an amount of 0.5 to 1 percent by weight (see the fourth paragraph on p. 5), and lecithin as an emulsifier.³ The reference differs from the instant claims insofar as an enzyme stabilizing metal chelate or antioxidation agent is not specifically disclosed. The general suggestion to use "stabilizing" agents is clearly made, however, at the penultimate paragraph of p. 4.

The secondary reference discloses stain-removing oral compositions containing enzymes such as papain (col. 3, lines 4-12), and agents which "stabilize enzymes in a dentifrice environment", including EDTA and sodium gluconate at concentrations of from 0.01 to 1% (preferably 0.1 to 0.5%), or sodium bisulfite, metal gallates, sodium stannate and ascorbic acid at

¹ Applicant should note that since the applied secondary reference is available under 35 U.S.C. 102(a), this ground of rejection cannot be overcome by a showing that the reference is disqualified under 35 U.S.C. 103(c) as prior art in a rejection under 35 U.S.C. 103(a).

² Contrary to Applicant's arguments otherwise, incorporation of the enzyme in the external coating layer of chewing gum which is not heated (see the second full paragraph on p. 4 of the translation) is not excluded by the language of instant claim 30 which requires, only very generally, that the claimed composition be "processed at a temperature of less than about 80 degrees Celsius." Including the enzyme in the non-heated coating is a type of "processing", where that term is interpreted as broadly as is reasonable in light of the teachings of the specification.

³ A combination of 0.5 to 3.0 percent by weight lecithin, and 0.1 to 1 percent by weight glycerin, as required by instant claim 43 is not specifically disclosed. It would have been obvious in a self-evident manner, however, to have used the two in combination, given their individual disclosures by the prior art. Moreover, it would have been obvious to have determined a workable percentage of lecithin using no more than routine experimentation, thus arriving at the claimed value of 0.5 to 3.0 percent. (This position is fully consistent with established precedent which holds that normally, changes in values are not patentable where the difference involved is one of degree, not of kind. See, e.g., *In re Aller* 105 USPQ 233, 235 (CCPA 1955); *In re Boesch*, 205 USPQ 215 (CCPA 1980); and *In re Peterson*, 315 F.3d 1325 (C.A. Fed. 2003). Furthermore, note that the reference itself suggests the use of "stabilizers, emulsifiers, humecants, dissolution regulators, flavorings, coating and polishing materials in "variable quantities" at the second line under the Table at p. 6).

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concentrations of from 0.1 to 1.5%, and preferably 0.3 to 0.75%. (See the first paragraph of col. 5). It differs from the instant claims insofar as it does not specifically disclose chewing gums.

It would have been obvious to have incorporated a chelating agent (e.g., EDTA) or antioxidation agent (e.g., sodium stannate) into the chewing gum compositions of the primary reference, motivated by the desire to increase enzyme stability as taught by the secondary reference.

2) Claims 26, 27, 44 and 45 are rejected under 35 U.S.C. 103(a) as being obvious over Hernandez (ES 2 131 006) in view of Gebreselassie et al (USP 6,379,654), the combination being taken further in view of Witzel et al (USP 4,238,475).

The primary and secondary references, and the motivation for combining their teachings, are discussed in subsection "1)" supra. Their combined teachings differ from the instant claims insofar as they are silent regarding the use of 0.1 to 1 percent by weight artificial sweeteners (instant claims 26 and 27) and 5 to 20 percent by weight calcium carbonate polishing agents (instant claims 44 and 45), respectively, although the primary reference does clearly suggest the use of "sweeteners" and "polishing agents" generally in the penultimate paragraph on page 4 of the translation.

The tertiary reference discloses various known additives for chewing gums. Since the reference is cited to show the general state of the art, it differs from the instant claims insofar as it does not specifically disclose enzyme-

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containing gums. Additives which are specifically disclosed include artificial sweeteners such as saccharin, aspartame and sodium cyclamate, which are used to provide initial burst of flavor (col. 5, lines 37-57; col. 9, lines 61-65); and texturizing agents such as calcium carbonate (col. 9, lines 58-61).

Established precedent holds that it is generally obvious to add known ingredients to known compositions with the expectation of obtaining their known function. See, e.g., In re Linder, 457 F.2d 506, 507 (CCPA 1972); see also In re Dial, 326 F.2d 430, 432 (CCPA 1964). Accordingly and consonant with the reasoning of such precedent, it would have been obvious to have used an artificial sweetener to provide an initial burst of flavor, or calcium carbonate to provide texture, in the chewing gum compositions suggested by the combined teachings of the primary and secondary references, since the use of these components is well-known in the art as taught by the tertiary reference. (Similarly, the selection of a workable percentage of each would likewise be obvious. See footnote 3 supra).

3) Claims 25, 28 and 29 are rejected under 35 U.S.C. 103(a) as being obvious over Hernandez (ES 2 131 006) in view of Gebreselassie et al (USP 6,379,654), the combination being taken further in view of Rapp et al (USP 6,180,143).

The primary and secondary references, and the motivation for combining their teachings, are discussed in subsection "1)" supra. In the interest of completeness of prosecution and with regard to this rejection only, and purely

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arguendo, the presumption will be made that the chewing gums of Hernandez have moisture contents higher than 5 percent by weight, and do not contain a sugar alcohol of a disaccharide.

The tertiary reference teaches that the addition of glucopyranosyl-sorbitol, alone or in mixture with glucopyranosyl-mannitol (both sugar alcohols of disaccharides specifically disclosed at p. 6, lines 9-14 of the instant specification) to chewing gums minimizes the undesirable moisture retention normally associated with non-cariogenic sweeteners such as sorbitol, mannitol and xylitol. See col. 1, lines 11-32. The former compounds may be used alone or as a partial replacement for the latter, so long as water absorption values are kept within acceptable limits. See col. 4, lines 16-32. The tertiary reference differs from the instant claims insofar as it is silent regarding the use of an enzyme such as papain.

The preferred sweeteners of the primary reference are sorbitol and xylitol, as previously discussed. Accordingly, it would have been obvious to have replaced those sweeteners in whole or in part with glucopyranosyl-sorbitol, motivated by the desire to minimize undesirable moisture retention as taught by the tertiary reference.

Action is Final, Necessitated by Amendment

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL.**

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See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Frederick F. Krass whose telephone number is 571-272-0580. The examiner's schedule is 9:30AM – 6:00PM, Monday through Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low can be reached at 571-272-0951. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Frederick Krass
Primary Examiner
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A handwritten signature in black ink, appearing to read 'Frederick Krass', written over the printed name.